

## § 73.1326

(2) Color additive mixtures for drug use made with ferric ferrocyanide may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications.* Ferric ferrocyanide shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Water soluble cyanide, not more than 10 parts per million.  
Lead (as Pb), not more than 20 parts per million.  
Arsenic (as As), not more than 3 parts per million.  
Nickel (as Ni), not more than 200 parts per million.  
Cobalt (as Co), not more than 200 parts per million.  
Mercury (as Hg), not more than 1 part per million.  
Oxalic acid, not more than 0.1 percent.  
Water soluble matter, not more than 3 percent.  
Volatile matter, not more than 10 percent.  
Total iron (as Fe corrected for volatile matter), not less than 37 percent and not more than 45 percent.

(c) *Uses and restrictions.* Ferric ferrocyanide may be safely used in amounts consistent with good manufacturing practice to color externally applied drugs including those intended for use in the area of the eye.

(d) *Labeling requirements.* The label of the color additive and of any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification requirements of section 721(c) of the act.

[43 FR 54235, Nov. 21, 1978]

## § 73.1326 Chromium hydroxide green.

(a) *Identity.* (1) The color additive chromium hydroxide green is principally hydrated chromic sesquioxide ( $\text{Cr}_2\text{O}_3 \cdot x\text{H}_2\text{O}$ ).

(2) Color additive mixtures for drug use made with chromium hydroxide green may contain only those diluents

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listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications.* Chromium hydroxide green shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Water soluble matter, not more than 2.5%.  
Chromium in 2% NaOH extract, not more than 0.1% as  $\text{Cr}_2\text{O}_3$  (based on sample weight).  
Boron (as  $\text{B}_2\text{O}_3$ ), not more than 8 percent.  
Total volatile matter at 1000 °C, not more than 20%.  
 $\text{Cr}_2\text{O}_3$  not less than 75%.  
Lead (as Pb), not more than 20 parts per million.  
Arsenic (as As), not more than 3 parts per million.  
Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions.* Chromium hydroxide green may be safely used in amounts consistent with good manufacturing practice to color externally applied drugs, including those for use in the area of the eye.

(d) *Labeling requirements.* The label of the color additive and of any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 36451, July 15, 1977, as amended at 42 FR 59852, Nov. 22, 1977]

## § 73.1327 Chromium oxide greens.

(a) *Identity.* (1) The color additive chromium oxide greens is principally chromic sesquioxide ( $\text{Cr}_2\text{O}_3$ ).

(2) Color additive mixtures for drug use made with chromium oxide greens may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications.* the color additive chromium oxide greens shall conform to the following specifications and shall be free from impurities other

than those named to the extent that such impurities may be avoided by good manufacturing practice:

Chromium in 2% NaOH extract, not more than 0.075% as  $\text{Cr}_2\text{O}_3$  (based on sample weight).

Arsenic (as As), not more than 3 parts per million.

Lead (as Pb), not more than 20 parts per million.

Mercury (as Hg), not more than 1 part per million.

$\text{Cr}_2\text{O}_3$ , not less than 95%.

(c) *Uses and restrictions.* Chromium oxide greens is safe for use in coloring externally applied drugs, including those intended for use in the area of eye, in amounts consistent with good manufacturing practice.

(d) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification pursuant to section 721(c) of the act.

[42 FR 36451, July 15, 1977]

#### § 73.1329 Guanine.

(a) *Identity.* (1) The color additive guanine is the crystalline material obtained from fish scales and consists principally of the two purines, guanine and hypoxanthine. The guanine content will vary from 75 to 97 percent, and the hypoxanthine will vary from 3 to 25 percent, depending on the particular fish and tissue from which the crystals are derived.

(2) Color additive mixtures for drug use made with guanine may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* The color additive guanine shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Guanine, not less than 75 percent.

Hypoxanthine, not more than 25 percent.

Ash (ignition at 800 °C), not more than 2 percent.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Assay, not less than 96 percent total purines.

Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions.* Guanine is safe for use in coloring externally applied drugs, including those intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(d) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification pursuant to section 721(c) of the act.

[42 FR 37537, July 22, 1977]

#### § 73.1375 Pyrogallol.

(a) *Identity.* The color additive pyrogallol is 1,2,3-trihydroxybenzene.

(b) *Specifications.* Pyrogallol shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Melting point, between 130° and 133 °C.

Residue on ignition, not more than 0.1 percent.

Lead (as Pb), not more than 20 p/m (parts per million).

Arsenic (as As), not more than 3 p/m.

(c) *Uses and restrictions.* Pyrogallol may be safely used in combination with ferric ammonium citrate (as listed in § 73.1025), for coloring plain and chromic catgut sutures for use in general and ophthalmic surgery, subject to the following restrictions:

(1) The dyed suture shall conform in all respects to the requirements of the United States Pharmacopeia XX (1980).

(2) The level of the ferric ammonium citrate-pyrogallol complex shall not